K052289

DEC 13 2005

510(k) Summary
for the Biowave
Deepwave Neuromodulation Pain Therapy Device

1. SPONSOR

Biowave Corporation
16 Knight Street
Norwalk, CT 06851

Contact Person: Brad Siff
Telephone: (203) 247-9020

Date Prepared: November 16, 2005

2. DEVICE NAME

Proprietary Name:	Deepwave Neuromodulation Pain Therapy Device
Common/Usual Name:	Electrical Muscle and Nerve Stimulator
Classification Names:	Powered Muscle Stimulator, Interferential Current Stimulator

3. PREDICATE DEVICES

Chattanooga Group Forte Model CPS 200 Stimulator Device K982828.

4. INTENDED USE

The Deepwave Neuromodulation Pain Therapy Device is indicated for:

- Symptomatic relief of chronic, intractable pain, post surgical and post-traumatic acute pain;
- Symptomatic relief of post-traumatic acute pain
- Symptomatic relief of post-operative pain

5. DEVICE DESCRIPTION

The Biowave Corporation Neuromodulation Pain Therapy Device is a battery-powered device intended to provide clinicians with the flexibility to prescribe powered muscle stimulation and TENS therapy. The device measures approximately 7.4 inches wide, 5.6 inches long, and 2.25 inches deep, weighs about 3 pounds, and operates on a 12 volt rechargeable NiMH battery that is enclosed within the unit. The unit will not operate while it is plugged into the wall to recharge the battery. The patient controls the amplitude of the signal with two buttons (a Plus (+) Button and a Minus (-) Button) on the face of the device. An LCD displays the amplitude of the signal in numerical format. Two wires emanate from the unit. One wire is attached to a large disposable electrode pad placed opposite the source of pain ("***Feed Pad***"). The second wire is attached to a smaller electrode pad ("***Pain Site Pad***") placed directly over the source of the pain (the treatment site).

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The Biowave Corporation Neuromodulation Pain Therapy is indicated for the following:

- Symptomatic relief of chronic, intractable pain, post surgical and post-traumatic acute pain;
- Symptomatic relief of acute pain
- Symptomatic relief of post-operative pain relief

These indications are identical to those indicated for the predicate device. Therefore, the indications for use of the Deepwave Neuromodulation Pain Therapy Device are essentially identical to those for predicate electrical stimulator devices that have been previously cleared for marketing in the United States.

The Biowave device and the Chattanooga device are similar in design and function. Both devices offer a biphasic waveform, sine waves and a beat frequency in the range of 100-200 Hz. Both the proposed and predicate devices are software driven TENs units that provide the user with a treatment program for pain reduction. The conclusion of this technical comparison is that the Biowave Deepwave Device is substantially equivalent to the predicate devices for the indications specified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2005

Biowave Corporation
c/o Mary McNamara-Cullinane
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K052289
Trade/Device Name: Deepwave Neuromodulation Pain Therapy Device
Regulatory Class: Unclassified
Product Codes: LIH
Dated: November 16, 2005
Received: November 17, 2005

Dear Mrs. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by

reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K052289

Device Name: *Deepwave Neuromodulation Pain Therapy Device*

The Deepwave Neuromodulation Pain Therapy Device is indicated for:

- Symptomatic relief of chronic, intractable pain, post surgical and post-traumatic acute pain;
- Symptomatic relief of post-traumatic acute pain
- Symptomatic relief of post-operative pain

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052289